

REMARKS

In the Office Action mailed December 9, 2004, claims 44-47 and 50-80 were pending. Claims 44, 47, and 60-80 stand rejected, and claims 45, 46 and 50-59 were objected to as depending from a rejected base claim but were indicated to be allowable if rewritten to include all the limitations of the base claim and any intervening claims. In this response claim 58 has been cancelled, and claims 47 and 71 have been amended. Reconsideration of the present application as amended and including claims 44-47, 50-58 and 60-80 in view of the remarks that follow is respectfully requested.

Claims 47 and 60-80 were rejected under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claims the subject matter which applicant regards as the invention. Specifically, it was asserted that use of "if, then" resulted in claiming the invention such that scope could not be determined. In this response, claims 47 and 70 have been amended to remove the conditional language in the claims and clarify the original scope of these claims. The amendments to claims 47 and 70 are not believed to be narrowing amendments, but rather are provided to remove the conditional language and clarify the scope of these claims. Withdrawal of this basis of the rejection of these claims is respectfully requested.

Claims 44, 47, 60-66 and 70-78 were rejected under 35 USC §102(e) as being anticipated by U.S. Patent No. 6,471,725 to Ralph et al. It is noted that Ralph et al. is provisionally prior art under 35 USC §102(e). Applicants reserve the right to swear behind the filing date of Ralph et al. with an affidavit under 37 CFR §1.131 in this application or in any related applications.

Assuming *arguendo* that Ralph et al. were prior art, it does not anticipate claims 44, 47, 60-66 and 70-78. "[A]n invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co. Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989.) The claims must not be treated as "mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning." Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al., 730 F.2d 1452, 1459, 221 USPQ 481, 486 (Fed. Cir. 1984). As a result, a reference that coincidentally lists features of a claim without describing the claimed arrangement, relationship, and organization of such features cannot anticipate.

The Office Action refers to the abstract of Ralph et al. It is noted that the abstract states the "set of spacers includes a porous spacer that is as wide as the spacer that restores the desired anatomical spacing. The porous spacer can therefore be left implanted in the intervertebral

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space....” These statements in the abstract are consistent with devices and methods disclosed in the specification of Ralph et al., which discloses distracting the disc space with trial spacers and removing the last inserted trial spacer that provides the desired disc space height. The desired disc space height is maintained with rod fixation apparatus engaged to the vertebrae, with surface plating and/or intervertebral cages, or by insertion of a bone graft or porous metal spacer “into the properly distracted intervertebral space.” *See, e.g.*, col. 3, line 8 to col. 8, line 50. Thus, Ralph et al. discloses that the trial spacer providing the desired disc space height is withdrawn from the disc space and is not employed to post-operatively maintain the desired disc space height. If a subsequent spacer device is inserted to post-operatively maintain the disc space, it is inserted in a “properly distracted” disc space since the spacer device has a height that corresponds to the height of the last inserted trial spacer. However, the last inserted trial spacer is not left in the spinal disc space.

Claim 44 is directed to a method for inserting an implant and recites “accessing a collapsed spinal disc space; sequentially inserting and removing a number of implants into the collapsed spinal disc space, each of said implants providing a different restored disc space height when inserted in the disc space, the spinal disc space at least partially collapsing when the inserted implant is removed therefrom; and leaving in the spinal disc space the implant from the number of implants providing a restored disc space height corresponding to a desired disc space height to post-operatively maintain the desired disc space height.” As discussed above, Ralph et al. discloses that the last inserted trial spacer providing the desired disc space height is removed. If a subsequent spacer device is inserted to post-operatively maintain the disc space. Any spacer implant is inserted in a “properly distracted” disc space since the spacer device has a height that corresponds to the height of the last inserted trial spacer. Ralph et al. does not disclose the method recited in claim 44 and therefore cannot anticipate it. Accordingly, withdrawal of this basis of the rejection of claim 44 is respectfully requested.

Amended claim 47 is directed to a method for inserting an implant and recites “accessing a collapsed spinal disc space from an uni-portal approach; inserting a first implant through the portal into the spinal disc space to provide a restored disc space height; removing the inserted first implant from the spinal disc space through the portal such that the spinal disc space is non-distracted; selecting a second implant from a number of implant subsequently inserted through the portal each providing a restored disc space height differing from the restored disc space height of the first implant and from one another, the selected second implant being the first of said number of implants providing a restored disc space height that corresponds to a desired disc space

height; and post-operatively maintaining the desired disc space height with the second implant in the spinal disc space.” As discussed above, Ralph et al. discloses that the last inserted trial spacer providing the desired disc space height is removed and does not post-operatively maintain the desired disc space height. If it is inserted, the subsequent implant has a height that is the same as that of the last inserted trial spacer, and is inserted into a properly distracted disc space. Ralph et al. therefore cannot anticipate claim 47 and withdrawal of this basis of the rejection of claim 47 is respectfully requested.

Claims 60-66 depending from claim 47 are allowable at least because claim 47 is allowable and for other reasons. For example, the leading ends of the trial spacers of Ralph et al. each have a differing height at their leading ends. Ralph et al. also does not disclose an implant with a maximum height between the leading and trailing ends of the implant. There is further no disclosure of a nose with a rounded surface profile extending between upper and lower vertebral endplate contacting surfaces. There is also no disclosure of parallel lateral surfaces for the spacers or the implants. Accordingly, withdrawal of this basis of the rejection of claims 60-66 is respectfully requested.

Claim 71 is directed to a method for restoring a collapsed spinal disc space and recites “providing a number of implants each having a body with a leading end nose defining a leading end height sized for insertion into a collapsed disc space and convexly curved upper and lower surfaces extending from the leading end nose to a trailing end of the body, the convexly curved upper and lower surfaces defining a maximum distraction height, each of the number of implants having the same leading end height and a differing maximum distraction height; inserting at least one of the number of implants into the collapsed spinal disc space, the spinal disc space being at least partially collapsed when the at least one implant is inserted; removing the at least one implant from the disc space; inserting at least one other of the number of implants with a greater distraction height into the collapsed spinal disc space when the at least one implant is removed, the spinal disc space being at least partially collapsed when the at least one implant is removed; and leaving in the spinal disc space the at least one other implant with the distraction height providing a desired disc space height to post-operatively maintain the desired disc space height.” As discussed above, Ralph et al. discloses that the last inserted trial spacer providing the desired disc space height is removed from the spinal disc space and does not post-operatively maintain the desired disc space height. Furthermore, Ralph et al. does not disclose an implant or a spacer with convexly curved upper or lower surfaces. Rather, the surfaces are either parallel or tapered.

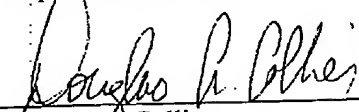
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Ralph et al. therefore cannot anticipate claim 71. Accordingly, withdrawal of this basis of the rejection of claim 71 is respectfully requested.

Claims 72-78 depending from claim 71 are allowable at least because claim 71 is allowable and for other reasons. For example, there is no disclosure of a nose with a rounded surface profile extending between upper and lower vertebral endplate contacting surfaces. There is also no disclosure of parallel lateral surfaces for the spacers or the implants. Accordingly, withdrawal of this basis of the rejection of claims 72-78 is respectfully requested.

Examination of the present application as amended and including claims 44-47, 50-58 and 60-80 in view of this response is respectfully requested. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the present application.

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